

## WHAT is CLAIMED is:

*Swal*

1. A method for decreasing serum cholesterol and increasing serum HDL in a patient comprising administering to the digestive tract of said patient an effective amount of a composition comprising a viable lactic acid-producing bacteria and a therapeutic agent selected from the group consisting of an effective amount of a cholesterol-reducing agent and a bifidogenic oligosaccharide.

2. The method of claim 1 wherein said lactic acid-producing bacteria is selected from the group consisting of non-pathogenic members of the Bacillus genus, Lactobacillus, Sporolactobacillus and Bifidobacterium.

3. The method of claim 2 wherein said lactic acid-producing Bacillus is selected from the group consisting of Bacillus coagulans, Bacillus coagulans Hammer, Bacillus brevis subspecies coagulans and Bacillus laevolacticus.

4. The method of claim 1 wherein said lactic acid-producing bacteria is Bacillus coagulans subspecies Hammer.

5. The method of claim 2 wherein said lactic acid-producing Lactobacillus is selected from the group consisting of Lactobacillus acidophilus, Lactobacillus casei, Lactobacillus DDS-1, Lactobacillus GG, Lactobacillus rhamnosus, Lactobacillus plantarum, Lactobacillus salivarius and Lactobacillus sporogenes (aka B. coagulans).

6. The method of claim 2 wherein said lactic acid-producing Sporolactobacillus is Sporolactobacillus P44.

7. The method of claim 2 wherein said lactic acid-producing Bifidobacterium is selected from the group consisting of Bifidobacterium adolescentis, Bifidobacterium animalis, Bifidobacterium bifidum, Bifidobacterium bifidus, Bifidobacterium breve, Bifidobacterium infantis, Bifidobacterium infantus and Bifidobacterium longum.

8. The method of claim 1 wherein said composition

contains  $10^5$  to  $10^{10}$  viable bacterium per gram of composition.

9. The method of claim 1 wherein said administering comprises oral ingestion of said composition.

5 10. The method of claim 1 wherein said administering comprises introducing into the digestive tract from 0.1 to 5 grams per day of said composition.

11. The method of claim 1 wherein said administering comprises introducing into the digestive tract from  $10^8$  to  
10  $10^{10}$  viable bacterium per day.

*Swat* 12. The method of claim 11 wherein said administering comprises introducing into the digestive tract from  $5 \times 10^8$  to  $10^9$  viable bacterium per day.

13. The method of claim 1 wherein said bifidogenic  
15 oligosaccharide is selected from the group consisting of fructo-oligosaccharide, gluco-oligosaccharide, and trisaccharide raffinose.

14. The method of claim 13 wherein fructo-oligosaccharide comprises polymers of fructose and glucose  
20 having a polymer chain length of from about 4 to 100 sugar units.

15. The method of claim 1 wherein said composition comprises about 10 milligrams to about 1 gram of bifidogenic oligosaccharide per gram of composition.

25 16. The method of claim 1 wherein said composition comprises from 100 to 500 milligrams of bifidogenic oligosaccharide per gram of composition.

17. The method of claim 1 wherein said administering comprises introducing into the digestive tract from 10  
30 milligrams to 20 grams of bifidogenic oligosaccharide per day.

18. The method of claim 17 wherein said administering comprises introducing into the digestive tract from 150

milligrams to 5 grams of bifidogenic oligosaccharide per day.

19. The method of claim 1 wherein said cholesterol-reducing agent is selected from the group consisting of a  
5 statin, a bile sequestering compound, a fiber product capable of binding cholesterol, niacin and aspirin.

20. The method of claim 19 wherein said statin is selected from the group consisting of cerivastatin, fluvastatin, lovastatin, pravastatin and simvastatin.

10 21. The method of claim 20 wherein said administering comprises introducing into the digestive tract from 10 to 80 milligrams of statin per day.

22. The method of claim 19 wherein said bile sequestering compound is selected from the group consisting  
15 of colestipol and cholestyramine.

23. The method of claim 22 wherein said administering comprises introducing into the digestive tract from 1 to 20 grams of bile sequestering compound per day.

*Suma3* 24. The method of claim 19 wherein said fibrin is  
20 selected from the group consisting of gemfibrozil, fenofibrate, psyllium, bran, glucomannan and Jerusalem artichoke flour.

25. The method of claim 24 wherein said administering comprises introducing into the digestive tract from 500  
25 milligrams to 50 grams of fibrin per day.

*Suma4* 26. The method of claim 1 wherein said compost further comprises a cholic acid complexation agent.

27. The method of claim 26 wherein said complexation agent is selected from the group consisting of a metal salt  
30 of calcium, chromium, copper, iodine, iron, magnesium, manganese, potassium, sodium and zinc.

28. The method of claim 27 wherein said metal salt is provided in the form of calcium citrate, potassium

gluconate, magnesium citrate or chromium picollinate.

29. The method of claim 1 wherein said composition further comprises a food substance, flavoring, vitamin or mineral.

5        30. The method of claim 1 wherein said patient is at risk for atherosclerosis, arterial sclerosis, myocardial infarction, heart attack, diabetes, coronary heart disease, angina pectoris or unstable angina.

10       31. A therapeutic composition for reduction of serum cholesterol comprising a viable lactic acid-producing bacteria and a therapeutic agent selected from the group consisting of an effective amount of a cholesterol-reducing agent and a bifidogenic oligosaccharide.

15       32. The composition of claim 31 wherein said lactic acid-producing bacteria is selected from the group consisting of non-pathogenic members of the *Bacillus* genus, *Lactobacillus*, *Sporolactobacillus* and *Bifidobacterium*.

20       33. The composition of claim 32 wherein said lactic acid-producing *Bacillus* is selected from the group consisting of *Bacillus coagulans*, *Bacillus coagulans* Hammer, *Bacillus brevis* subspecies *coagulans* and *Bacillus laevolacticus*.

25       34. The composition of claim 31 wherein said lactic acid-producing bacteria is *Bacillus coagulans* subspecies Hammer.

30       35. The composition of claim 32 wherein said lactic acid-producing *Lactobacillus* is selected from the group consisting of *Lactobacillus acidophilus*, *Lactobacillus casei*, *Lactobacillus* DDS-1, *Lactobacillus* GG, *Lactobacillus rhamnosus*, *Lactobacillus plantarum*, *Lactobacillus salivarius* and *Lactobacillus sporogenes* (aka *B. coagulans*).

36. The composition of claim 32 wherein said lactic

acid-producing Sporolactobacillus is Sporolactobacillus P44.

37. The composition of claim 32 wherein said lactic acid-producing Bifidobacterium is selected from the group consisting of Bifidobacterium adolescentis, Bifidobacterium animalis, Bifidobacterium bifidum, Bifidobacterium bifidus, Bifidobacterium breve, Bifidobacterium infantis, Bifidobacterium infantus and Bifidobacterium longum.

38. The composition of claim 31 wherein said composition contains  $10^5$  to  $10^{10}$  viable bacterium per gram of composition.

39. The composition of claim 31 wherein said bifidogenic oligosaccharide is selected from the group consisting of fructo-oligosaccharide, gluco-oligosaccharide, and trisaccharide raffinose.

40. The composition of claim 39 wherein fructo-oligosaccharide comprises polymers of fructose and glucose having a polymer chain length of from about 4 to 100 sugar units.

41. The composition of claim 31 wherein said composition comprises about 10 milligrams to about 1 gram of bifidogenic oligosaccharide per gram of composition.

42. The composition of claim 31 wherein said composition comprises from 100 to 500 milligrams of bifidogenic oligosaccharide per gram of composition.

43. The composition of claim 31 wherein said cholesterol-reducing agent is selected from the group consisting of a statin, a bile sequestering compound, a fiber product capable of binding cholesterol, niacin and aspirin.

44. The composition of claim 43 wherein said statin is selected from the group consisting of cerivastatin, fluvastatin, lovastatin, pravastatin and simvastatin.

45. The composition of claim 43 wherein said

composition comprises from 1 to 80 milligrams of statin per gram of composition.

46. The composition of claim 43 wherein said bile sequestering compound is selected from the group consisting of colestipol and cholestyramine.

47. The composition of claim 43 wherein said composition comprises from 0.1 to 0.8 grams of bile sequestering compound per gram of composition.

48. The composition of claim 43 wherein said fibrin is selected from the group consisting of gemfibrozil, fenofibrate, psyllium, bran, glucomannan and Jerusalem artichoke flour.

49. The composition of claim 43 wherein said composition comprises from 10 milligrams to 0.5 grams of fibrin per gram of composition.

50. The composition of claim 31 wherein said compost further comprises a cholic acid complexation agent.

51. The composition of claim 50 wherein said complexation agent is selected from the group consisting of a metal salt of calcium, chromium, copper, iodine, iron, magnesium, manganese, potassium, sodium and zinc.

52. The composition of claim 51 wherein said metal salt is provided in the form of calcium citrate, potassium gluconate, magnesium citrate or chromium picollinate.

53. The composition of claim 31 wherein said composition further comprises a food substance, flavoring, vitamin or mineral.

54. A therapeutic system for reducing serum cholesterol comprising a container comprising a label and a composition comprising a culture of viable lactic acid-producing bacteria and a therapeutic agent selected from the group consisting of an effective amount of a cholesterol-reducing

agent and a bifidogenic oligosaccharide, wherein said label comprises instructions for use of the composition for reduction of serum cholesterol.

55. The system of claim 54 wherein said lactic acid-producing bacteria is selected from the group consisting of non-pathogenic members of the *Bacillus* genus, *Lactobacillus*, *Sporolactobacillus* and *Bifidobacterium*.

56. The system of claim 55 wherein said lactic acid-producing *Bacillus* is selected from the group consisting of *Bacillus coagulans*, *Bacillus coagulans* Hammer, *Bacillus brevis* subspecies *coagulans* and *Bacillus laevolacticus*.

57. The system of claim 55 wherein said lactic acid-producing bacteria is *Bacillus coagulans* subspecies Hammer.

58. The system of claim 55 wherein said lactic acid-producing *Lactobacillus* is selected from the group consisting of *Lactobacillus acidophilus*, *Lactobacillus casei*, *Lactobacillus* DDS-1, *Lactobacillus* GG, *Lactobacillus rhamnosus*, *Lactobacillus plantarum*, *Lactobacillus salivarius* and *Lactobacillus sporogenes* (aka *B. coagulans*).

59. The system of claim 55 wherein said lactic acid-producing *Sporolactobacillus* is *Sporolactobacillus* P44.

60. The system of claim 55 wherein said lactic acid-producing *Bifidobacterium* is selected from the group consisting of *Bifidobacterium adolescentis*, *Bifidobacterium animalis*, *Bifidobacterium bifidum*, *Bifidobacterium bifidus*, *Bifidobacterium breve*, *Bifidobacterium infantis*, *Bifidobacterium infantus* and *Bifidobacterium longum*.

61. The system of claim 54 wherein said composition contains  $10^5$  to  $10^{10}$  viable bacterium per gram of composition.

62. The system of claim 54 wherein said bifidogenic oligosaccharide is selected from the group consisting of fructo-oligosaccharide, gluco-oligosaccharide, and

trisaccharide raffinose.

63. The system of claim 62 wherein fructo-  
oligosaccharide comprises polymers of fructose and glucose  
having a polymer chain length of from about 4 to 100 sugar  
5 units.

64. The system of claim 54 wherein said composition  
comprises about 10 milligrams to about 1 gram of bifidogenic  
oligosaccharide per gram of composition.

65. The system of claim 54 wherein said composition  
10 comprises from 100 to 500 milligrams of bifidogenic  
oligosaccharide per gram of composition.

66. The system of claim 54 wherein said cholesterol-  
reducing agent is selected from the group consisting of a  
statin, a bile sequestering compound, a fiber product  
15 capable of binding cholesterol, niacin and aspirin.

67. The system of claim 66 wherein said statin is  
selected from the group consisting of cerivastatin,  
fluvastatin, lovastatin, pravastatin and simvastatin.

68. The system of claim 66 wherein said composition  
20 comprises from 1 to 80 milligrams of statin per gram of  
composition.

69. The system of claim 66 wherein said bile  
sequestering compound is selected from the group consisting  
of colestipol and cholestyramine.

70. The system of claim 66 wherein said composition  
25 comprises from 0.1 to 0.8 grams of bile sequestering  
compound per gram of composition.

71. The system of claim 66 wherein said fibrin is  
selected from the group consisting of gemfibrozil,  
30 fenofibrate, psyllium, bran, glucomannan and Jerusalem  
artichoke flour.

72. The system of claim 66 wherein said composition  
comprises from 10 milligrams to 0.5 grams of fibrin per gram



of composition.

73. The system of claim 54 wherein said compost further comprises a cholic acid complexation agent.

74. The system of claim 54 wherein said complexation agent is selected from the group consisting of a metal salt of calcium, chromium, copper, iodine, iron, magnesium, manganese, potassium, sodium and zinc.

75. The system of claim 74 wherein said metal salt is provided in the form of calcium citrate, potassium gluconate, magnesium citrate or chromium picollinate.

76. The system of claim 54 wherein said composition further comprises a food substance, flavoring, vitamin or mineral.

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